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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,090	11/15/2001	Gordhanbhai Patel	PATL3.0-010	6317

7590 09/29/2004

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/009,090	Applicant(s) PATEL	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 27-44 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on July 8, 2004.

Claims 1-49 are pending.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-9, 15-21, 24, 27-35, 37-44, 48 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,287,518 to Ignacio et al.

Ignacio et al teach a composition and device for monitoring sterilization processes. The composition comprises a dye (indicator) and a halogen source (activator) within a binder resin (polymer), as recited in claim 1 and 42 (col. 3, lines 8-9). The dye is one that is susceptible to halogenation, as recited in claim 5. Phenol red, a pH indicator, is taught as an example, as recited in claims 3 and 4 (col. 3, lines 10-19). With respect to claim 6, Ignacio et al teach an example of a sterilization monitoring composition where phenol red is used as the indicator. After exposure to peracetic acid, the composition turned from red to yellow (col. 10, line 66 – col. 11, line 15). With respect to the activator, Ignacio teaches halogen sources including as alkali metal halides such as potassium bromide, as recited in claims 16-19 (col. 3, lines 31-39). The reference also teaches using quaternary amines, such as tetra alkyl ammonium bromides, as recited in claims 19 - 21 (col. 6, lines 57-60). With respect to the binder resin (polymer),

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Ignacio et al teach cellulosic materials that are water soluble (col. 3, lines 40-53). With respect to claim 24, Ignacio et al teach using a microporous bottom (40) which helps control the amount of vapor that contacts the indicator composition (col. 10, lines 18-19). With respect to claims 27 and 28, figure 1 of the reference shows a multi-layered device wherein the top layer (30) is made of polymeric material (col. 10, lines 4-6). With respect to claims 30-35, where Applicants claim the process of making the device, Ignacio teaches dissolving the components of the composition in an alcohol solvent and applying the composition to blotter paper (col. 4, lines 38-62). The composition may be in the form of ink and the substrate may be in the form of a strip or label (col. 3, line 64 – col. 4, line 19). With respect to claims 40-41, where Applicants claim the use of the device in monitoring sterilization processes, Ignacio et al teach that the device may be used to monitor peracetic acid or hydrogen peroxide sterilization processes (col. 5, lines 49-59). Ignacio et al further teach that the sterilization indicators may be used to monitor sterilization processes that include a plasma step, as recited in claims 37 and 49.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 22, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al in view of EP 0356116 to Suto.

The disclosure of Ignacio et al is described above. Ignacio et al differ from the instantly claimed invention in that there is no teaching of thiocyanates in the sterilization monitoring compositions. Ignacio et al also fail to teach the use of plasticizers in the composition.

Suto teaches compositions useful in monitoring sterilization processes. The reference teaches that thiocyanates, sodium thiocyanate in particular, aid in accelerating the reaction of the indicator to form an observable color change (page 3, lines 42-49). It would have been obvious to one of ordinary skill in the art to include sodium thiocyanate in the composition of Ignacio et al to activate the indicator and allow the color reaction to proceed faster and quickly alert the user as to the accuracy of the sterilization process.

With respect to the use of plasticizers, Suto teaches that plasticizers are commonly added to ink compositions used in sterilization processes. It would have been obvious to one of ordinary skill in the art to add a plasticizer to the composition of Ignacio et al to modify the manner in which vapor contacts the indicator composition.

6. Claims 9-14, 36, and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al in view of US Patent 5,622,764 to Battles.

The disclosure of Ignacio et al is described above. Ignacio et al differ from the instantly

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claimed invention in that while Ignacio et al teach cellulosic materials as the polymer, the particular polymers recited in claims 9-14, 36, and 45-47 are not disclosed.

Battles teaches sterilization indicators. The indicators of Battles comprise an indicator ink in combination with a binder. The indicator ink and binder are printed onto a backing material. Battles teaches that binders, such as nitrocellulose and acrylate polymers, allow the indicator ink to be maintained on the backing material (col. 3, lines 49-53; col. 4, lines 3-5; col. 8, lines 59-67). It would have been obvious to one of ordinary skill in the art to use nitrocellulose or acrylate polymers as the binders for the sterilization indicators of Ignacio et al to assure that the indicator compositions is capable of being maintained on the substrate materials.

#### *Allowable Subject Matter*

7. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record fails to teach or suggest including zinc compounds or polyaziridine into sterilization compositions to aid in controlling the diffusion of vapor gases.

#### *Response to Arguments*

8. Applicant's arguments filed July 8, 2004 have been fully considered but they are not persuasive.

In response to the anticipatory rejection over Ignacio et al, Applicants argue that the indicator device of Ignacio et al would not be suitable for monitoring plasma sterilization

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because the paper in the indicator device would automatically turn the device off. In response, the Examiner does not consider this argument to be persuasive because firstly, Ignacio et al teach that the devices may be used to monitor sterilization processes that include a plasma step. Applicants discount this statement and argue that the devices would be unsuitable for plasma monitoring. Secondly, Ignacio et al teach using substrates other than paper, such as polyester and plastic (col. 3, line 64 – col. 4, line 14). Thus, even if the paper substrates would be unsuitable, Ignacio et al clearly teaches using other types of substrates. Further, Applicants claims that their device uses a polymeric substrate instead of a paper substrate. It should be noted that a polymeric substrate is not a limitation in independent claims 1, 30, 37, 42, 48 or 49. In fact, Applicants' own specification (page 17) and claim (32) recite the use of paper as the substrate. If plasma monitoring is not suitable using device having paper substrates, Applicants should amend their claims to incorporate substrates that are suitable for such monitoring.

Applicants further argue that the color change that would result in using the instant device is based on hydrohalogenation, whereas the color change of the device taught by Ignacio et al is based on halogenation. In response, the Examiner notes that the device of Ignacio et al comprises the same components as the device recited in claims 1 and 42. Ignacio et al teach a sterilization monitoring device comprising a polymer, indicator dye and an activator. Ignacio et al teach the same dyes and activator as those claimed by Applicants. Given this, it is unclear as to how the device of Ignacio et al would not operate in the same manner as the device instantly claimed or how the color reaction from the device of Ignacio et al would be any differ from the color reaction of the instantly claimed device – especially since the reagents (indicator

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dye and activator) are the same and the both devices may be subject to hydrogen peroxide sterilization processes.

As another alleged difference, Applicants note that the instant invention results in a color change that is uniform across the entire test strip, whereas the Ignacio reference teaches that the color change spreads from one edge to the center. In response, Applicants are attempting to argue how their device operates differently than the device described in Ignacio et al. Because the device claims are limited only by structural components, the manner in which the device operates does not limit the claims sufficiently to patentably distinguish over Ignacio et al. See MPEP 2114.

Further, Applicants argue that the present invention does not include a vapor head space and a barrier film. In response, Ignacio et al teach as their preferred embodiment, the use of a housing having a vapor head space and a barrier. The basic indicator of Ignacio et al comprises an indicator dye, activator and binder present on a substrate, just as claimed by Applicants. Further, it should be noted that Applicants' claims recite "comprising", which is considered to be open language that does not exclude the presence of features not recited. See MPEP 2111.03.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until



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after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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